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10/510,497	10/07/2004	Shunji Hayashi	Q84102	1554
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EXAMINER				
BADR, HAMID R				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/510,497

Applicant(s)

HAYASHI ET AL.

Examiner

HAMID R. BADR

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 5-6, and 8-10 are objected to for being improperly multiply dependent claims. Claim 3 is already multiply dependent. Therefore, multiple dependent claims 5 and 6 will be improperly dependent on claim 3. Claim 6 is multiply dependent, and therefore multiple dependent claims 8-10 will be improperly dependent on claim 6, 8, and/or 9. In the interest of compact prosecution, claims 5-6 and 8-10 have been treated as if they were properly dependent and further treated on the merits as set forth below.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura et al. (EP 1 112 692 A1, hereinafter R1) in view of Mäyrä-Mäkinen et al. (US 5908646, hereinafter R2)

Regarding Claim 1

3. R1 teaches the use of *Lactobacillus gasseri*, with a disinfection property against *Helicobacter pylori*, in foods [001].

4. R1 characterizes their *Lactobacillus gasseri* OLL 2716 to have high survival when applied to food products (page 3, lines 20-21). They further disclose the storage

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temperature of 10°C and viable count of 10⁷ cfu/ml of yogurt after 2 weeks (page 8, lines 5-7). Yogurt is a high water activity (a_w) food product compared to semi-hard or hard cheeses. Cheese, especially hard cheese, has a much lower water activity and under the conditions of lower water activity survival rate will be high. Consequently the limitation of claim 1 regarding the viable counts will depend on how many viable bacteria are initially present. The initial population will have a much higher survival rate when stored under the storage conditions of temperature as taught by R1.

Regarding Claim 2

5. R1 discloses that their *Lactobacillus gasseri* is highly gastric acid resistant and grows well under conditions at low pH [0010]. Given that the pH in human stomach is about 2, the *L. gasseri* disclosed by R1 can tolerate very low pH of human stomach.

Regarding Claim 3

6. R1 explains the use of *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) in foods (Abstract and [0013, 0014, 0015]). Given that this organism is exactly the same as the organism in claim 3, R1 teaches that the claimed organism can be used in foods.

Regarding Claim 5

7. R1 discusses the use of *Lactobacillus gasseri* in foods, in food components and in combination with other foods [0017].

Regarding Claim 10

8. The use of *Lactobacillus gasseri* in foods and pharmaceuticals is discussed by R1 as discussed above.

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9. R1 is silent regarding the incorporation of *L. gasseri* in cheese.
10. The incorporation of lactobacilli, for their antagonistic properties into cheese, is explored by R2. R2 discloses an anticlostridial *Lactobacillus rhamnosus*, which can be used to prevent problems caused by clostridia in a number of different fields (Col. 5, lines 39-42) including the protection of food. R2 further mentions that it is possible to employ strains of *Lactobacillus rhamnosus* for medical purposes (Col. 5, lines 47-48). Incorporation of lactobacilli into Swiss and Edam cheeses are discussed in detail (Example 3 and 4). Growing the lactobacillus species (LC 705) at 37°C for 24 hours and the population of organisms grown (5×10^8 /ml) are taught in Example 3.

Regarding Claim 6

11. The cheese making process is well known in the art. Further more since yeast extract is used for the culture of Lactobacilli, the culture of Lactobacilli being added to the milk before the formation of the curd will always carry some yeast extract with it. Furthermore, in the cheese making industry, the addition of any starter culture will take place before the formation of a curd. The incubation of the molded and pressed cheese is also a known practice in the industry. For example, in cheddar cheese making, after the cheddaring process, the cheese is molded and pressed to form big blocks of cheese which is incubated and aged as such. As a result the limitations of claim 6 are all known in the industry.

Regarding Claim 7

12. Incubation of the molded and pressed curd will be an extension of the incubation period for a starter culture. This is performed in order to increase the number of viable bacteria in the curd. Incubating the curd without cooling it will allow the *Lactobacilli* to proliferate more and increase in number.

Regarding Claim 8

13. *Lactobacillus gasseri* is a mesophilic organism. R1 demonstrates that growth is impaired at 15°C (page 3, B-Physiological properties). It is obvious to incubate a microorganism in a range suitable for growth and proliferation. Incubation of an organism in a medium for growth and proliferation is normally done for 24 hours. The incubation time limitation of claim 8 is a usual incubation time.

Regarding Claim 9

14. The lactobacilli starter cultures in the cheese industry may be added to the raw milk.

15. It would have been obvious to one of ordinary skill in the art, at the time the invention was made to modify the teachings of R1 and incorporate the anti-helicobacter *L. gasseri* of R1, which can be grown in a food, into cheese as taught by R2. One would have done so to benefit from a more shelf stable product such as cheese as compared to yogurt taught by R1. Absent any evidence to contrary and based on the combined teachings of the cited references, there would have been a reasonable expectation of success in making a cheese containing *L. gasseri*.

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16. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura et al. (EP 1 112 692 A1, hereinafter R1) in view of Germond et al. (WO 0188150, hereinafter R3).

17. R1 teaches the use of *Lactobacillus gasseri*, with a disinfection property against *Helicobacter pylori*, in foods [001].

18. R1 characterizes their *Lactobacillus gasseri* OLL 2716 to have high survival when applied to food products (page 3, lines 20-21). They further disclose the storage temperature of 10°C and viable count of 10⁷ cfu/ml of yogurt after 2 weeks (page 8, lines 5-7). Yogurt is a high water activity (a_w) food product compared to semi-hard or hard cheeses. Cheese, especially hard cheese, has a much lower water activity and under the conditions of lower water activity survival rate will be high. Consequently the limitation of claim 1 regarding the viable counts will depend on how many viable bacteria are initially present. The initial population will have a much higher survival rate when stored under the storage conditions of temperature as taught by R1.

Regarding Claim 2

19. R1 discloses that their *Lactobacillus gasseri* is highly gastric acid resistant and grows well under conditions at low pH [0010]. Given that the pH in human stomach is about 2, the *L. gasseri* disclosed by R1 can tolerate very low pH of human stomach.

Regarding Claim 3

20. R1 explains the use of *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) in foods (Abstract and [0013, 0014, 0015]). Given that this organism is exactly the same as the organism in claim 3, R1 teaches that the claimed organism can be used in foods.

Regarding Claim 5

21. R1 discusses the use of *Lactobacillus gasseri* in foods, in food components and in combination with other foods [0017].

Regarding Claim 10

22. The use of *Lactobacillus gasseri* in foods and pharmaceuticals is discussed by R1 as discussed above.

23. R1 is silent regarding the incorporation of *L. gasseri* in cheese.

24. R3 discloses the incorporation of *L. gasseri* in dairy products including cheese. R1 claims *Lactobacillus gasseri* as one of the lactic acid bacteria (claim 2) which can be added to a food product (claim 7) and the food product include cheese, yogurt, fermented milks, ice cream (claims 8-9).

Regarding Claim 6

25. The cheese making process is well known in the art. Further more since yeast extract is used for the culture of *Lactobacilli*, the culture of *Lactobacilli* being added to the milk before the formation of the curd will always carry some yeast extract with it. Furthermore, in the cheese making industry, the addition of any starter culture will take place before the formation of a curd. The incubation of the molded and pressed cheese is also a know practice in the industry. For example, in cheddar cheese making, after the cheddaring process, the cheese is molded and pressed to form big blocks of cheese which is incubated and aged as such. As a result the limitations of claim 6 are all known in the industry.

Regarding Claim 7

26. Incubation of the molded and pressed curd will be an extension of the incubation period for a starter culture. This is performed in order to increase the number of viable bacteria in the curd. Incubating the curd without cooling it will allow the *Lactobacilli* to proliferate more and increase in number.

Regarding Claim 8

27. *Lactobacillus gasseri* is a mesophilic organism. R1 demonstrates that growth is impaired at 15°C (page 3, B-Physiological properties). It is obvious to incubate a microorganism in a range suitable for growth and proliferation. Incubation of an organism in a medium for growth and proliferation is normally done for 24 hours. The incubation time limitation of claim 8 is a usual incubation time.

Regarding Claim 9

28. The lactobacilli starter cultures in the cheese industry may be added to the raw milk.

29. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of R1 and incorporate the organism into cheese as taught by R3. One would have done so to make a cheese containing *L. gasseri* and a longer shelf life as offered by cheese. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in making a cheese containing *L. gasseri*.

Response to Arguments

30. Applicants' arguments have been fully considered. Based on the following reasons, those arguments are not deemed persuasive.

31. Applicant's argument that the inhibition of *H. pylori* is meant in the human stomach does not differentiate it from the organism disclosed by R1 characterized as anti *H. pylori*. It does not matter where the pathogen is. The organism disclosed by R1 which happens to be exactly the same as the claimed organism is clearly anti *H. pylori*. The relationship between the high bacterial count maintained in the cheese and the attribute of being anti *H. pylori* is not clear. The applicant is putting these two attributes together without showing the significance of this association.

32. While R2 discloses the use of *L. rhamnosus* in cheese, it does not claim the anti-helicobacter property. R1 is only teaching that Lactobacilli can be incorporated into cheese regardless of their function and this is what is needed to make the invention of the present application. Two elements are known: *Lactobacillus gasseri* is anti-helicobacter and *Lactobacilli* may be incorporated in cheese. Thus, it would have been obvious to one of ordinary skill in the art to incorporate the *L. gasseri* from R1 into cheese.

33. The shelf life of the cheese having viable organisms is important. However, adding an organism to the cheese and storing it at 10C for six months and finding the survival rate would be only a test. Any other Lactobacilli would probably do the same thing as long as the environment in the cheese is appropriate especially regarding the oxygen toxicity and the water activity of the cheese (moisture content).

34. The teachings of R3 are further proof that *L. gasseri* can be incorporated into cheese. Since the *L. gasseri* is being used as a probiotic in R3, the viable organisms at certain counts per gram of cheese would be inherent in the teachings of R3.

35. R1 characterizes their *Lactobacillus gasseri* OLL 2716 to have high survival when applied to food products (page 3, lines 20-21). They further disclose the storage temperature of 10°C and viable count of 10^7 cfu/ml of yogurt after 2 weeks (page 8, lines 5-7). Yogurt is a high water activity (a_w) food product compared to semi-hard or hard cheeses. Cheese, especially hard cheese, has a much lower water activity and under the conditions of lower water activity survival rate will be high. Consequently the limitation of claim 1 regarding the viable counts will depend on how many viable bacteria are initially present. The initial population will have a much higher survival rate when stored under the storage conditions of temperature as taught by R1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794